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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/776,022	02/09/2004	Ramez Emile Necola Shehada	064693-0101	9082

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EXAMINER

HILL, LAURA C

ART UNIT	PAPER NUMBER
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3761

DATE MAILED: 10/18/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

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APPLICATION NO/ CONTROL NO.	FILING DATE	FIRST NAMED INVENTOR / PATENT IN REEXAMINATION	ATTORNEY DOCKET NO.
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EXAMINER
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ART UNIT
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PAPER
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Commissioner for Patents

<b>Office Action Summary</b>	Application No. 10/776,022	Applicant(s) NECOLA SHEHADA ET AL.	
	Examiner Laura C. Hill	Art Unit 3761	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 17-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 09 February 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>1/4, 3/31, &amp; 6/15/05</u> . | 6) <input type="checkbox"/> Other: ____.  |

**DETAILED ACTION**

***Election/Restrictions***

- I. Claims 1-1, drawn to a surgical drain, classified in class 604, subclass 541.
- II. Claims 18-20, drawn to a method of utilizing a surgical drain, classified in class 604, subclass 541.

Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the process for using the surgical drain can be practiced with another materially different product such as any type of surgical drain (i.e. drain having a conduit with first surface on the inside of the conduit, etc.).

Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Group II, restriction for examination purposes as indicated is proper.

During a telephone conversation with Marc Brown on 22 September 2005, a provisional election was made without traverse to prosecute the invention of Group I, claims 1-16. Affirmation of this election must be made by applicant in replying to this Office action.

Claims 17-20 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

### ***Specification***

1. The disclosure is objected to because of the following informalities: the 'first sensing system' as recited in claim 1 is referred to as 'plurality of sensors 12' on page 8 of the specification.

Appropriate correction is required to improve consistency.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-4, 9-10 and 12-16 are rejected under 35 U.S.C. 102(b) as being anticipated by Johnson (US 3,866,599; herein 'Johnson'). Regarding claims 1, 12 and 15-16 Johnson discloses a surgical drain 1 comprising an elongated conduit with first and opposing second outer side surfaces configured to be implanted in and to drain

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from a body cavity tissue (col. 1, ll. 7-10, figure 1); a first optical fiber/sensing system 11, 21, 27 and a second optical fiber/sensing system 11, 21, 27 (col. 2, ll. 44-49).

Regarding claim 2 Johnson discloses the optical fibers/sensors determine physiological properties such as oxygen saturation and pressure (col. 1, ll. 16-22 and 33-36).

Regarding claim 3 Johnson discloses the optical fibers/sensors transmit energy to and receive energy from body tissue (col. 1, ll. 20-25).

Regarding claims 4 and 10-11 Johnson discloses third and fourth optical fibers/sensing systems 11, 21, 27 that are distinct sensing systems from the first and second optical fibers and thus are capable of each sensing different properties. If a prior art structure is capable of performing the intended use as recited in the preamble, then it meets the claim. See, e.g., In re Schreiber, 128 F.3d 1473, 1477, 44 USPQ2d 1429, 1431 (Fed. Cir. 1997).

Regarding claim 9 Johnson discloses the surgical drain comprises an oximeter that receives energy from the optical fibers 11, 21, 27 and provides measurements (col. 2, ll. 63-col. 3, line 5. Since the oximeter provides measurements to the user, it is capable of displaying these measurements to the user. If a prior art structure is capable of performing the intended use as recited in the preamble, then it meets the claim. See, e.g., In re Schreiber, 128 F.3d 1473, 1477, 44 USPQ2d 1429, 1431 (Fed. Cir. 1997).

Regarding claims 13-14 Johnson discloses the elongated conduit 2 further comprises housing 20; the housing 20 supports optical fibers 11, 21, 27 and are thus embedded and affixed inside housing 20 of conduit (col. 3, ll. 6-9).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Johnson (US 3,866,599; herein 'Johnson') as applied to claim 1 above, and further in view of Russo et al. (US 4,317,452; herein 'Russo'). Johnson discloses a surgical drain 1 having a conduit configured to rest against a length of tissue within the body and having a lumen 22 (figures 1-6, col. 2, ll. 29-col. 3, line 5). Johnson *does not expressly disclose* the surgical drain comprises a plurality of drain holes. **Russo** discloses a surgical drain comprising a conduit 10 having a plurality of holes along the entire length of the drain portion, which allows body fluids in the cavity to pass into and along the conduit into a drainage site (fig. 1, col. 2, ll. 7-19, col. 4, ll. 56). One would be motivated to modify the surgical drain of Johnson with the plurality of drain holes of Russo to provide a means to drain body fluids and since both references disclose surgical drains for insertion into the

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body proximate tissue. Therefore, it would be obvious to one of ordinary skill in the art at the time the invention was made to modify the surgical drain, thus providing a plurality of drain holes.

4. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Johnson (US 3,866,599; herein 'Johnson') as applied to claim 1 above, and further in view of Harautuneian et al. (US 4,684,694), Koehn (US 3,030,953), Santomieri (US 3,515,137) and Beck (US 3,537,451). Johnson discloses catheter materials such as nylon, Teflon®, polyvinylchloride, polyurethane, polyethylene, etc (col. 5, ll. 15-20). Johnson *does not expressly disclose* the conduit material is optically transparent. It is well known to use transparent polyvinylchloride, polyethylene, polytetrafluoroethylene (also known as Teflon®), and polyurethane materials for catheters as taught by Harautuneian, Koehn, Santomieri and Beck. One would be motivated to modify the catheter material of Johnson with the optically transparent catheter materials of Harautuneian, Koehn, Santomieri and Beck to provide a means to see the first and second sensing systems through the conduit and since both references disclose the aforementioned materials for use in catheters. Therefore, it would be obvious to one of ordinary skill in the art at the time the invention was made to modify the catheter material, thus providing an optically transparent material.

5. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Johnson (US 3,866,599; herein 'Johnson') as applied to claim 1 above, and further in view of Sadowski (US 3,614,737; herein 'Sadowski'). Johnson *does not expressly disclose* a processing system to compare differences in physiological properties. It is well known



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that processing systems compare differences in data as taught by **Sadowski** (col. 1, ll. 71-col. 2, line 6). Therefore, it would be obvious to one of ordinary skill in the art at the time the invention was made to modify the drain, thus providing a processing system to compare differences in physiological data.

6. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Johnson (US 3,866,599; herein 'Johnson') as applied to claim 1 above, in view of Sadowski (US 3,614,737; herein 'Sadowski'), and further in view of Leist (US 4,432,365; herein 'Leist'). Johnson/Sadowski disclose the processing system to compare differences as discussed above with respect to claim 7. Johnson/Sadowski *do not expressly disclose* the sensing systems sense temperature. **Leist** discloses it is known to build temperature sensors into transcutaneous physiological sensing units for medical diagnostic purposes (col. 1, ll. 68-col. 2, line 2). Therefore, it would be obvious to one of ordinary skill in the art at the time the invention was made to modify the sensing system, thus providing temperature sensors in the sensing systems.

### ***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Martin (US 4,631,061) is cited for showing a surgical drain attached to outside of body cavity with first sensing system 60,66,68 that senses liquid rather than tissue and optical fiber elements 66,68 that pair with light beam 67 to activate vacuum pump 43 to move through the collection device. Plicchi et al. (US 2002/0123674) is cited for showing implantable therapeutic and diagnostic device of pulmonary tissue via multiple thermal flow sensors.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura C. Hill whose telephone number is 571-272-7137. The examiner can normally be reached on Monday through Friday (off every other Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Laura C. Hill  
Examiner  
Art Unit 3761

LCH



**TATYANA ZALUKAEVA**  
**SUPERVISORY PRIMARY EXAMINER**

